

**Appl. No.** : 10/633,726  
**Filed** : August 4, 2003

### **REMARKS**

New Claims 15-17 have been added directed to treating uterine fibroids by applying high intensity focused ultrasound energy selectively to the uterine fibroid base. Support for these claims may be found in the specification, for example, on page 13, lines 8-17 and Figures 9A and 9B. Claims 10-17 are pending. The Applicants have carefully considered all of the Examiner's rejections but respectfully submit that the claims are allowable for at least the following reasons.

#### Rejection under § 102

The Examiner maintained the rejection of Claim 10 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,425,867 (Vaezy et al.). The Examiner stated that she did not understand the Applicants' argument regarding the teaching of the provisional application to which Vaezy claims priority. The Examiner asserted that the provisional application extensively teaches the treatment of fibroids using ultrasound. However, Applicants' argument is not that the provisional does not teach treatment of fibroids. Rather, the Applicant's argument is that the provisional application does not teach treating a uterine fibroid by targeting tissues to cause a decrease in blood supply to the fibroid. Claim 10 requires pre-selecting treatment sites so that necrosing tissues at the treatment sites causes a decrease in blood supply to the fibroid. Vaezy did not disclose focusing HIFU on "a selected portion of [the] tumor" so as to cause "lesions of the blood vessels supplying oxygen and nutrients to the tumor" until the September 17, 1999 filing. Vaezy, column 16, lines 51-56. The September 18, 1998 provisional application does not contain this language or in any other way suggest treating fibroids by targeting tissues to cause a decrease in blood supply to the fibroid. Accordingly, the Applicants respectfully submit that because their invention date is prior to September 17, 1999 (as demonstrated by the previously-submitted § 1.131 declaration), Vaezy is not prior art and does not anticipate Claim 10.

The Applicants further note that Vaezy does not disclose the application of high intensity focused ultrasound selectively to the uterine fibroid base from a plurality of angles around the circumference of the uterine fibroid. Accordingly, Claims 15-17 are not anticipated by Vaezy.

#### Rejections under § 103

The Examiner maintained rejections of Claims 11-14 under 35 U.S.C. § 103(a) as being obvious over Vaezy in view of U.S. Patent No. 5,601,526 (Chapelon et al.). The Examiner asserts that the ultrasonic waves taught by Chapelon have the same effect as the claimed

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ultrasonic energy. However, Chapelon discloses "pre-heating" of the focal region. Chapelon, column 7, line 48 and Figure 3. In contrast, Claims 11-14 require "pre-focal heating." Heating of tissue in front the focal region (as in Applicants' invention) has a substantially different effect than heating of tissue at the focal region (as in Chapelon). Chapelon does not teach to heat tissue at any locations other than the focal region. In fact, Chapelon teaches away from such heating by expressing avoiding "heat spreading around the focus point." Chapelon, column 2, line 3. A *prima facie* case of obviousness requires that all of the claim limitations are taught or suggested by the prior art. See M.P.E.P. § 2143.03. The Examiner has yet to identify any disclosure in Chapelon that teaches or suggests heating tissue outside of the focal region. Thus, the Applicants respectfully submit that the Examiner has not made a *prima facie* case of obviousness of Claims 11-14.

The Applicants further note that neither Vaezy nor Chapelon teach or suggest the application of high intensity focused ultrasound selectively to the uterine fibroid base from a plurality of angles around the circumference of the uterine fibroid. Accordingly, Claims 15-17 are not obvious over Vaezy in view of Chapelon.

### CONCLUSION

By the foregoing amendments and remarks, the Applicants respectfully submit that they have overcome all of the Examiner's rejections and respectfully request a timely issuance of a Notice of Allowance.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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